

Application Serial No. 09/720,762

Attorney Docket No. 114174.00014

Amendment and Response to Office Action, Submitted April 2, 2007

**REMARKS/ARGUMENTS**

Claims 1, 3 and 6-9, 11 and 13-40 are now pending, a total of 35 claims.

Dependent claim 41 is cancelled. Claims 1, 9, 22 and 32 are independent.

**I. New Matter and Written Description Rejections**

The Office Action mailed October 2, 2006 raised § 132 "new matter" and § 112, first paragraph issues relating to the limitation "only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated" in claims 1, 18, 32 and 41. Dependent claim 41 is cancelled. Independent claim 33 is now amended to recite the limitations of claim 41.

The limitation "only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated" is fully supported by the original disclosure. The Specification, at page 3, states:

The peripheral side surface that is in contact with the syringe barrel or the bottom surface that is in contact with the liquid can be laminated with polyethylene fluoride resin."

This statement expressly provides that *either* the peripheral side surface *or* the bottom surface may be laminated with polyethylene fluoride resin. In at least this manner, selective lamination of the peripheral side surface is disclosed.

In addition, the Specification teaches that the peripheral side surface alone may be coated with silicon. Specifically, the Specification, at page 3, states:

Silicon may be applied to the peripheral side surface of the gasket that is in contact with the inner surface of the syringe barrel, but it is preferable that silicon is not applied to the bottom syringe that is in contact with the liquid charged into the syringe barrel.

This statement explicitly prohibits silicon lamination of the bottom surface of the syringe that is in contact with liquid. The Specification, at page 1, explains: "if silicon applied to a gasket is mixed into chemical liquid, it becomes foreign matter." In other words, if using silicon, only the

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peripheral side surface of the gasket should be laminated. Thus, the original disclosure fully supports selective lamination of the gasket, as recited in claims 1, 18, 32 and newly amended claim 33.

Accordingly, claims 1, 18, 32 and 33, as presented, meet the requirements of 35 U.S.C. §§ 112 and 132. No new matter has been introduced.

## II. Independent Claim 1

Claims 1, 3, 6-10, 12, 16-18, 23 and 30-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull (U.S. 6,080,136), and Sudo et al. (U.S. 5,009, 646).

Independent claim 1 recites as follows:

1. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

Neither Trull nor Sudo teach or suggest selectively applying a coating to a surface of a syringe gasket. Trull does not teach or even suggest gasket lamination. Sudo does not teach or suggest selectively applying a laminate to gasket surfaces. Thus, nothing in Trull or Sudo – individually or in combination – teach or suggest laminating “only the peripheral side surface that contacts the inner surface of the syringe barrel,” as recited in claim 1.

In addition, the Office Action states that it would have been obvious “to modify the Trull et al. gasket by using a gasket material of polyethylene, as taught by Sudo et al.” The Office Action however cites no evidence of what was known at the time the invention was made. To establish a prima facie case of obviousness, motivation to combine references must be

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supported by "substantial evidence" (MPEP § 2143.01, 2144.-2144.09), not mere conclusory statements about what might have been "basic knowledge" or "common sense" to one of ordinary skill in the art before the invention. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001). Therefore, Applicant respectfully requests a reference or an affidavit to support any alleged "motivation to combine" Trull with Sudo to laminate "only the peripheral side surface that contacts the inner surface of the syringe barrel." See 37 C.F.R. § 1.104(d)(2).

Claim 1 is patentable over the combination of Trull and Sudo. No motivation to combine Trull and Sudo has been shown. Claim 1 should be allowed.

### III. Independent Claim 9

Independent claim 9 recites as follows:

9. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a first tapered slant, and a second tapered slant is formed between the peripheral side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction.

In respect of claim 9, the Office Action states that it would have been obvious to modify the Trull gasket with lamination as taught by Sudo. As noted above, Trull does not teach or suggest laminating a syringe gasket in any matter, and motivation to combine Trull with Sudo

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has not been shown. For at the least reasons discussed above, a prima facie obviousness has not been established. Claim 9 is patentable over the combination of Trull and Sudo.

#### IV. Independent claim 23

Independent claim 23 recites as follows:

23. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

In respect of claim 23, the Office Action states that it would have been obvious to combine Trull and Sudo to achieve the claimed invention. As discussed, prima facie obviousness has not been shown. Claim 23 is also patentable over the art of record.

#### V. Independent Claim 33

Claims 33-37 and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. in view of Smith et al. (5,597, 530).

Independent claim 33 is currently amended, and recites as follows:

33. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side

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surface that contacts the inner surface of the syringe barrel is laminated with silicon.

Independent claim 33, as amended, is patentable over the cited references. The Office Action states that Smith discloses that a syringe gasket is coated with silicon. Smith does not teach or suggest selectively applying a coating to a gasket surface. For at least the reasons discussed above, the art of record does not teach or suggest selectively applying silicon to a portion of the gasket such that another portion of the gasket is not coated with silicon. Amended claim 33 may be allowed.

#### VI. Dependent Claims

Dependent claims 3, 6-8, 10-22, 24-32 and 34-40 are patentable with the independent claims set forth above. These dependent claims recite additional features that further distinguish the cited references.

In view of the foregoing, Applicant respectfully submits that the claims are in condition for allowance and therefore requests reconsideration of the application. The Examiner may telephone Applicant's undersigned counsel at the number below concerning this application.

Also enclosed is a Petition for Extension of Time for three (3) months.

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Dated: April 2, 2007

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